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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,379	02/12/2002	Houssam Ibrahim	2590-35	3689

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EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,379	IBRAHIM ET AL.	
	Examin r	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicants' Response and Amendment filed on June 26, 2003.

Claim Rejections - 35 USC § 112

Claims 12-14 provide for the use of flasks, syringes and perfusion bags to preserve a pharmaceutical preparation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). While the claims have been amended to better reflect U.S. practice for method claims, the claims still only recite an use without setting forth any steps involved in the process. Therefore, the claims are treated as improper use claims. It is suggested to expressly state a process step for the method claims to be proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites that the "solvent comprises besides water". It is unclear what the solvent comprises from this recitation. It is suggested that the language be amended to better clarify what the solvent comprises or does not comprise.

Claim 11 recites that in the process/method of step a) that a quantity of oxaliplatinum is "put in contact at a temperature inferior to 80 degrees C". It is unclear if the temperature is to be higher or lower than 80 degrees C to be inferior. It is suggested that the claim be amended to better clarify the temperature range at which the step is intended to take place, for examples at "a temperature less than 80 degrees C", if that is what applicants intend to convey.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ibrahim et al. (US 5716988) in combination with Schilpalius (US 5897871) or Blackshear et al. (US 4439181). Ibrahim teaches a solution of oxaliplatinum and water for administration through injection of infusion (Col. 2, lines 9-19). The concentration of the oxaliplatinum is from 1 to 5 mg/ml (Col. 2, lines 9-19). The solution can be sealed in a vial infusion pouch, an ampoule or carried in an injection micropump (Col. 2, lines 54-63). The method of preparation is recited in Example 1 at Col. 3. Ibrahim does not expressly teach the exact concentration for the oxaliplatinum nor does the reference teach other solvents for the solution.

Schlipalius and Blackshear each teach that active agents can be in solution with glycerol and can be administered by injection or infusion (Col. 7, Claims 1-5; and Col. 3, line 15 – Col. 14, line 36, respectively).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a suitable solvent to prepare injection or infusion solution for administration that include oxaliplatinum and glycerol in differing concentrations.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). The

Examiner does not see the criticality in the particular concentrations for oxaliplatinum compound. The prior art teaches the compound to have the same activity in a concentration close of the claimed concentration. Any difference is a matter of degree and not of kind.

One of ordinary skill in the art would have been motivated to do this to prepare a pharmaceutically active solution that implements a solution that is non-toxic, is a normal component of human and animal tissues and plasma, and maintains the fluidity of the solution without loss of the biological activity.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed June 26, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to teach or suggest a composition containing oxaliplatinum in solution with one of the recited hydroxylated derivatives. Further, applicants argue there is no motivation to combine the references cited in the Office Action.

It is the position of the Examiner that the prior art teaches parenteral compositions of oxaliplatinum at certain concentrations. The secondary references teach known excipients or solvents for parenteral compositions. No criticality is seen in the inclusion of these components or in the claimed concentrations. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process

of normal optimization. No superior or unexpected results have been shown. Therefore, the rejections under 35 USC 103 are maintained.

Conclusion

Due to the new grounds of rejection under 112, 2nd paragraph, this action is deemed non-final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600